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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
Separate paging is given to this Part in order that it may be filed as a separate compilation.

RAJYA SABHA

The following Bill was introduced in the Rajya Sabha on 21st August, 2007:—

BILL NO. LVII OF 2007

A Bill further to amend the Drugs and Cosmetics Act, 1940.

BE it enacted by Parliament in the Fifty-eighth Year of the Republic of India as follows:—

Short title and commencement.

1. (*1*) This Act may be called the Drugs and Cosmetics (Amendment) Act, 2007.

(*2*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint:

Provided that different dates may be appointed for different provisions of this Act, and any reference in any such provision to the commencement of this Act shall be construed as a reference to the coming into force of that provision.

Amendment of section 3.

23 of 1940.

2. In the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the principal Act), in section 3,—

(*i*) for clause (*aa*), the following clauses shall be substituted, namely:—

'(*aa*) "Central Drugs Authority" means the Central Drugs Authority of India constituted under sub-section (*1*) of section 5;

(*aai*) "Chairperson" means the Chairperson of the Central Drugs Authority;

(*aaii*) "clinical trial" means systematic study of any drug or cosmetic in human subjects to generate data for discovering or verifying its clinical, pharmacological (including pharmacodynamic and pharmacokinetic) or adverse effects with the objective of determining safety, efficacy or tolerance of the drug or the cosmetic;';

(*ii*) in clause (*b*), for sub-clause (*iv*), the following sub-clause shall be substituted, namely:—

"(*iv*) such medical device, medicated device, instrument, apparatus, appliance, material, software necessary for their application, intended for internal or external use in human beings or animals, whether used alone or in combination, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Central Drugs Authority, for the purpose of diagnosis, prevention, monitoring, treatment or mitigation of any disease or disorder; diagnosis, monitoring, treatment, alleviation of or compensation for, any injury or handicap; investigation, replacement or modification of anatomy or physiology; or control of conception, and which does not achieve its intended action primarily by any pharmacological or immunological or metabolical process, but is included in the pharmacopoeias mentioned in the Second Schedule;";

(*iii*) after clause (*b*), the following clauses shall be inserted, namely:—

'(*bb*) "Drugs Controller (India)" means the Drugs Controller (India) appointed under sub-section (*1*) of section 5E;

(*bbb*) "Fund" means the Fund constituted under sub-section (*1*) of section 5-I;';

(*iv*) in clauses (*c*) and (*e*), for the words "Central Government", wherever they occur, the words "Central Drugs Authority" shall be substituted;

(*v*) in clause (*f*), for the words "sale or distribution", the words "sale or export or distribution" shall be substituted;

(*vi*) after clause (*f*), the following clause shall be inserted, namely:—

'(*ff*) "Member" means a Member of the Central Drugs Authority and includes the Chairperson;';

(*vii*) in clause (*h*), in sub-clause (*ii*), for the words "Drugs Technical Advisory Board constituted under section 5", the words "Central Drugs Authority" shall be substituted.

Insertion of new Chapters.

3. In the principal Act, after Chapter I, the following Chapters shall be inserted, namely:—

'CHAPTER IA

CENTRAL DRUGS AUTHORITY OF INDIA

Constitution of Central Drugs Authority.

5. (*1*) The Central Government shall, by notification in the Official Gazette, constitute an Authority to be known as the Central Drugs Authority of India.

(*2*) The Central Drugs Authority shall be a body corporate by the name aforesaid,

having perpetual succession and a common seal with power, subject to the provisions of this Act, to acquire, hold and dispose of property, both movable and immovable, and to contract, and may, by the said name, sue or be sued.

(*3*) The Central Drugs Authority shall consist of a Chairperson and not more than five, but at the least three, Members, to be appointed by the Central Government by notification in the Official Gazette.

(*4*) The headquarters of the Central Drugs Authority shall be at Delhi.

(*5*) The Central Drugs Authority may, by notification in the Official Gazette, establish its offices at such other places in India as it considers necessary.

Qualifications of Chairperson and Members.

5A. The Chairperson and Members of the Central Drugs Authority shall be appointed by the Central Government from amongst persons who have special knowledge of, and at the least fifteen years' professional experience in pharmaceutical industry, research or teaching, or public administration, finance or law:

Provided that a person who is, or has been, in the service of Government shall not be appointed as a Chairperson or Member unless such person has held the post of Secretary or Additional Secretary to the Government of India or any equivalent post in the Central Government or a State Government or a Public Sector Undertaking.

Term of office of Chairperson and Members.

5B. The Chairperson or Member shall hold office as such for a term of three years from the date on which he enters upon his office, and shall be eligible for reappointment for a further term of three years:

Provided that the Chairperson or Member shall not hold office as such on attaining the age of seventy years.

Salaries, allowances, pensions and other conditions of service of Members.

5C. The salaries, allowances and pensions payable to, and other conditions of service of, the Members shall be such, as may be prescribed by the Central Government.

Vacancies, etc., not to invalidate proceedings.

5D. No act or proceeding of the Central Drugs Authority shall be invalidated merely by reason of—

(*a*) any vacancy in, or any defect in the constitution of, the Central Drugs Authority;

(*b*) any defect in the appointment of a person as a Member of the Central Drugs Authority; or

(*c*) any irregularity in the procedure of the Authority not affecting the merits of the case.

Staff of the Central Drugs Authority.

5E. (*1*) The Central Drugs Authority shall appoint a Drugs Controller (India), and such other officers and employees as it considers necessary for the efficient discharge of its functions and exercise of its powers under this Act.

(*2*) The salaries, allowances and pensions payable to, and other conditions of service of, the Drugs Controller (India), other officers and employees of the Central Drugs Authority appointed under sub-section (*1*) shall be such as may be determined by the Central Drugs Authority by regulations.

(*3*) The Drugs Controller (India) shall be the Secretary of the Central Drugs Authority.

Powers and functions of Central Drugs Authority.

5F. (*1*) The Central Drugs Authority may issue licences under clause (*c*) of section 10, clause (*c*) of section 18 and clause (*c*) of section 33EEC, and collect fees therefor.

(*2*) The Central Drugs Authority may cancel or suspend any licence issued under sub-section (*1*).

(*3*) The Central Drugs Authority shall collect charges for granting permission for conduct of clinical trials in respect of drugs and cosmetics.

(*4*) The Central Drugs Authority may constitute such committees or sub-committees as it considers essential for the efficient discharge of its functions and exercise of its powers under this Act.

(*5*) The Central Drugs Authority shall recommend to the Central Government—

(*a*) standards for drugs and cosmetics;

(*b*) the Central Drugs Laboratories for the purpose of testing drugs and cosmetics;

(*c*) measures to regulate import of drugs and cosmetics;

(*d*) measures to regulate manufacture for sale or for export or for distribution, or sale, stock or exhibition of drugs and cosmetics;

(*e*) standards for good manufacturing and laboratory practices and other such practices;

(*f*) measures to regulate clinical trials;

(*g*) amounts of fees and other charges payable under this Act;

(*h*) any other measures for the purpose of giving effect to the provisions of this Act.

(*6*) The Central Drugs Authority shall regulate its own procedure.

Powers and functions of Drugs Controller (India).

5G. (*1*) The Drugs Controller (India) shall exercise the powers conferred upon him under this Act or the rules framed thereunder or assigned to him by the Central Drugs Authority.

(*2*) The Drugs Controller (India) shall be the Chief Executive Officer and the legal representative of the Central Drugs Authority, and shall be responsible for—

(*a*) the day-to-day administration of the Central Drugs Authority;

(*b*) drawing up of proposals for the work programmes of the Central Drugs Authority;

(*c*) implementing the work programmes approved and the decisions made by the Central Drugs Authority;

(*d*) the preparation of the statement of revenue and expenditure and the execution of the budget of the Central Drugs Authority;

(*e*) the preparation of draft annual report for submission to and approval of the Central Drugs Authority.

(*3*) The Drugs Controller (India) shall have administrative control over other officers and employees of the Central Drugs Authority.

Grants by Central Government.

5H. The Central Government may, after due appropriation made by Parliament by law in this behalf, make to the Central Drugs Authority grants of such sums of money as are required by it.

Fund.

5-I. (*1*) There shall be constituted a Fund to be called the Central Drugs Authority of India Fund and there shall be credited thereto—

(*a*) all grants, fees and charges received by the Central Drugs Authority under this Act; and

(*b*) all sums received by the Central Drugs Authority from such other sources as may be determined by the Central Government.

(*2*) The Fund shall be applied for meeting—

(*a*) the salaries, allowances and pensions payable to the Chairperson and other Members and the administrative expenses, including the salaries, allowances and pensions payable to or in respect of the Drugs Controller (India) and other officers and employees of the Central Drugs Authority; and

(*b*) the expenses to carry out the objects and purposes of this Act.

Accounts and audit.

5J. (*1*) The Central Drugs Authority shall maintain proper accounts and other relevant records and prepare an annual statement of accounts in such form as may be prescribed by the Central Government in consultation with the Comptroller and Auditor-General of India.

(*2*) The accounts of the Central Drugs Authority shall be audited by the Comptroller and Auditor-General of India at such intervals as may be specified by him and any expenditure incurred in connection with such audit shall be payable by the Central Drugs Authority to the Comptroller and Auditor-General of India.

(*3*) The Comptroller and Auditor-General of India and any other person appointed by him in connection with the audit of the accounts of the Central Drugs Authority shall have the same rights and privileges and authority in connection with such audit as the Comptroller and Auditor-General generally has, in connection with the audit of the Government accounts and, in particular, shall have the right to demand the production of books, accounts, connected vouchers and other documents and papers and to inspect any of the offices of the Central Drugs Authority.

(*4*) The accounts of the Central Drugs Authority as certified by the Comptroller and Auditor-General of India or any other person appointed by him in this behalf, together with the audit report thereon, shall be forwarded annually to the Central Government and that Government shall cause the same to be laid, as soon as may be after it is received, before each House of Parliament.

Annual report.

5K. (*1*) The Central Drugs Authority shall prepare every year an annual report in such form and manner and at such time as may be prescribed by the Central Government, giving summary of its activities during the previous year and copies of the report shall be forwarded to the Central Government.

(*2*) A copy of the report forwarded under sub-section (*1*) shall be laid, as soon as may be after it is received, before each House of Parliament.

Power to make rules.

5L. (*1*) The Central Government may, after consultation with, or on the recommendation of, the Central Drugs Authority and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter:

Provided that consultation with the Central Drugs Authority may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Central Drugs Authority shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Central Drugs Authority may make in relation to the amendment of the said rules.

(*2*) Without prejudice to the generality of the foregoing power, such rules may provide for the following matters, namely:—

(*a*) the salaries, allowances and pensions payable to, and other conditions of service of, the Members under section 5C;

(*b*) the manner and form in which the accounts of the Central Drugs Authority shall be maintained under sub-section (*1*) of section 5J;

(*c*) the form and manner in which and the time within which annual report is to be made to the Central Government under sub-section (*1*) of section 5K.

Power to make regulations.

5M. (*1*) The Central Drugs Authority may, by notification in the Official Gazette, make regulations consistent with this Act and the rules made thereunder, to discharge its functions and exercise its powers.

(*2*) In particular, and without prejudice to the generality of the foregoing power, such regulations may provide for the following matters, namely:—

(*a*) the salaries, allowances and pensions payable to, and other conditions of service of, the Drugs Controller (India) and other officers and employees of the Central Drugs Authority under sub-section (*2*) of section 5E;

(*b*) the regulation of the procedure of the Central Drugs Authority under sub-section (*6*) of section 5F.

CHAPTER IB

CLINICAL TRIALS

No clinical trial without permission

5N. No person shall conduct clinical trials in respect of any drug or cosmetic except under, and in accordance with, the permission granted by the Central Drugs Authority.

Punishment for conducting clinical trial without permission.

5-O. (*1*) Whoever, himself or by any other person on his behalf, conducts clinical trials in contravention of section 5N shall be punished with imprisonment for a term which may extend to five years and with fine which may extend to ten lakh rupees.

(*2*) Whoever having been convicted of an offence under sub-section (*1*) is again convicted of an offence under that sub-section, shall be punished with imprisonment for a term which may extend to ten years and with fine which may extend to twenty lakh rupees.

Trial of offences.

5P. (*1*) No prosecution under section 5-O shall be instituted except upon complaint made in writing in this behalf by an officer authorised by the Central Drugs Authority.

(*2*) No Court inferior to that of a Metropolitan Magistrate or of a Judicial Magistrate of the first class shall try an offence punishable under section 5-O.

Power to make rules.

5Q. (*1*) The Central Government may after consultation with, or on the recommendation of, the Central Drugs Authority and after pervious publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter:

Provided that consultation with the Central Drugs Authority may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Central Drugs Authority shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Central Drugs Authority may make in relation to the amendment of the said rules.

(*2*) Without prejudice to the generality of the foregoing power, such rules may provide for the form and conditions of the permission under section 5N, the charges payable therefor, and the cancellation or suspension of such permission in any case where any provision of this Act or the rules made thereunder is contravened or any of the conditions subject to which the permission is granted is not complied with.'.

Substitution of heading of Chapter II.

4. In the principal Act, in Chapter II, for the Chapter heading "THE DRUGS TECHNICAL ADVISORY BOARD, THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE", the Chapter heading "THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE" shall be substituted.

Omission of section 5.

5. In the principal Act, section 5 shall be omitted.

Amendment of section 6.

6. In the principal Act, in section 6,—

(*a*) for the word " Laboratory", wherever it occurs, the words " Laboratory or Laboratories" shall be substituted;

(*b*) in sub-section (*2*), for the word "Board", the words "Central Drugs Authority" shall be substituted.

Amendment of section 7.

7. In the principal Act, in section 7,—

(*a*) in sub-section (*1*), for the words "Drugs Technical Advisory Board", the words "Central Drugs Authority" shall be substituted;

(*b*) for sub-section (*2*), the following sub-section shall be substituted, namely:—

"(*2*) the Drugs Consultative Committee shall consist of such number of representatives of the Central Government, industry, consumer associations, academic and research institutions, as may be prescribed and one representative of each State Government to be nominated by the State Government concerned.";

(*c*) after sub-section (*3*), the following sub-section shall be inserted, namely:—

"(*4*) The Central Government may, after consultation with the Central Drugs Authority, make rules prescribing the number of representatives under sub-section (*2*).".

Omission of section 7A.

8. In the principal Act, section 7A shall be omitted.

Amendment of section 8.

9. In the principal Act, in section 8, in sub-section (*2*), for the word "Board", the words "Central Drugs Authority" shall be substituted.

Amendment of section 10.

10. In the principal Act, in section 10, in the second proviso, for the word "Board", the words "Central Drugs Authority" shall be substituted.

Amendment of section 12.

11. In the principal Act, in section 12,—

(*a*) in sub-section (*1*), for the word "Board", wherever it occurs, the words "Central Drugs Authority" shall be substituted;

(*b*) in sub-section (*2*), in clause (*a*), the words "the authority empowered to issue the same" shall be omitted.

Amendment of section 16.

12. In the principal Act, in section 16, in sub-section (*2*), for the word "Board", the words "Central Drugs Authority" shall be substituted.

Amendment of section 18.

13. In the principal Act, in section 18,—

(*a*) for the words "manufacture for sale or for distribution", wherever they occur, the words "manufacture for sale or for export or for distribution" shall be substituted;

(*b*) in the second proviso, for the word "Board", the words "Central Drugs Authority" shall be substituted.

Amendment of sections 20 and 21.

14. In the principal Act, in sections 20 and 21, for the words "Central Government", wherever they occur, the words "Central Drugs Authority" shall be substituted.

Amendment of section 22.

15. In the principal Act, in section 22, in sub-section (*1*), in clause (*cca*), for the words "manufacture for sale or for distribution", the words "manufacture for sale or for export or for distribution" shall be substituted.

Amendment of sections 27 and 27A.

16. In the principal Act, in sections 27 and 27A, for the words "manufactures for sale or for distribution", at both the places where they occur, the words "manufactures for sale or for export or for distribution" shall be substituted.

Amendment of section 31.

17. In the principal Act, in section 31, in sub-section (*1*), in clause (*ii*), for the words "manufacture for sale, or for distribution", the words "manufacture for sale or for export or for distribution" shall be substituted.

Amendment of section 33.

18. In the principal Act, in section 33,—

(*a*) in sub-section (*1*), for the word "Board", wherever it occurs, the words "Central Drugs Authority" shall be substituted;

(*b*) in sub-section (*2*),—

(*i*) clause (*b*) shall be omitted;

(*ii*) in clause (*e*),—

(*A*) for the words "manufacture for sale or for distribution", the words "manufacture for sale or for export or for distribution" shall be substituted; and

(*B*) the words "the authority empowered to issue the same, the qualifications of such authority" shall be omitted;

(*iii*) clause (*n*) shall be omitted.

Omission of section 33C.

19. In the principal Act, section 33C shall be omitted.

Amendment of section 33D.

20. In the principal Act, in section 33D,—

(*a*) in sub-section (*1*), for the words "Ayurveda, Siddha and Unani Drugs Technical Advisory Board", the words "Central Drugs Authority" shall be substituted;

(*b*) for sub-section (*2*), the following sub-section shall be substituted, namely:—

"(*2*) The Ayurvedik, Siddha and Unani Drugs Consultative Committee shall consist of such number of representatives of the Central Government, industry, consumer associations, academic and research institutions, as may be prescribed and one representative of each State Government to be nominated by the State Government concerned.".

Amendment of section 33EEB.

21. In the principal Act, in section 33EEB, for the words "manufacture for sale or for distribution", the words "manufacture for sale or for export or for distribution" shall be substituted.

Amendment of section 33EEC.

22. In the principal Act, in section 33EEC,—

(*A*) in clause (*a*), for the words "manufacture for sale or for distribution", the words "manufacture for sale or for export or for distribution" shall be substituted;

(*B*) in clause (*c*),—

(*i*) for the words "manufacture for sale or for distribution", the words "manufacture for sale or for export or for distribution" shall be substituted; and

(*ii*) the words "by the prescribed authority" shall be omitted.

Amendment of sections 33F and 33G.

23. In the principal Act, in sections 33F and 33G, for the words "Central Government", wherever they occur, the words "Central Drugs Authority" shall be substituted.

Amendment of section 33-I.

24. In the principal Act, in section 33-I, for the words "manufactures for sale or for distribution", the words "manufactures for sale or for export or for distribution" shall be substituted.

25. In the principal Act, in section 33L, for the words "manufacture for sale", at both the places where they occur, the words "manufacture for sale or for export or for distribution" shall be substituted. Amendment of section 33L.

26. In the principal Act, in section 33N,— Amendment of section 33N.

(*a*) in sub-section (*1*), for the word "Board", wherever it occurs, the words "Central Drugs Authority" shall be substituted;

(*b*) in sub-section (*2*),—

(*i*) clause (*b*) shall be omitted;

(*ii*) in clause (*e*),—

(*A*) for the words "manufacture for sale", the words "manufacture for sale or for export or for distribution" shall be substituted; and

(*B*) the words "the authority empowered to issue the same" shall be omitted;

(*iii*) after clause (*f*), the following clause shall be inserted, namely:—

"(*ff*) prescribe the number of representatives under sub-section (*2*) of section 33 D;".

27. In the principal Act, in section 33-O, for the word "Board", the words "Central Drugs Authority" shall be substituted. Amendment of section 33-O.

28. In the principal Act, for section 38, the following section shall be substituted, namely:— Substitution of new section for section 38.

"38. Every rule and every regulation made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation.". Rules and regulations to be laid before Parliament.

STATEMENT OF OBJECTS AND REASONS

The Drugs and Cosmetics Act, 1940 (the Act) is a consumer protection legislation, which is mainly concerned with the standards and quality of durgs and regulates the import, manufacture, sale and distribution of drugs and cosmetics.

2. The Central Government had constituted an Expert Committee under the chairmanship of Dr. R.A. Mashelker, Director General of the Council of Scientific and Industrial Reaserch in January 2003 to undertake a comprehensive examination of drug regulatory issues, including the problem of spurious drugs and to suggest measures to improve the drug administration in the country. The Committee, *inter alia,* recommended setting up of a Central Drugs Authority reporting directly to the Ministry of Health and Family Welfare and a system of centralised licensing. The Central Government considered the recommendations of the Committee and proposes to make amendments in the Act, in order to facilitate setting up of a Central Drugs Authority and introduction of Centralised licensing for manufacture of drugs in pursuance of the said recommendations. The Drugs and Cosmetics (Amendment) Bill, 2007, *inter alia,* provides for:—

(*a*) substitution of the "Drugs Technical Advisory Board" as well as the "Drugs Technical Advisory Board for Ayurvedic, Siddha and Unani Drugs" by the "Central Drugs Authority";

(*b*) insertion of a new Chapter IA with a view to providing the constitution of the Central Drugs Authority and other connected or incidental matters;

(*c*) insertion of a new Chapter IB in the Act, providing for grant of permission for clinical trials, punishment for conducting clinical trial without permission, trial of offences, etc.; and

(*d*) expansion of the compositions of the Drugs Consultative Committees.

3. Certain consequential changes in the Act are also proposed so as to make it in consonance with proposal for setting up of the Central Drugs Authority.

4. The Bill seeks to achieve the above objects.

ANBUMANI RAMADOSS.

Notes on clauses

Clause 1 relates to short title and commencement of the Act.

Clause 2 amends section 3 of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the Act) in order to add definitions of the terms "Central Drugs Authority", "Chairperson", "Member", "Drugs Controller (India)", "clinical trial" and "Fund", amend the definition of the term "drug", and substitute the words "Central Government" in the definitions of the terms "Government analyst" and "Inspector" with the words "Central Drugs Authority", the words "sale or distribution" in the definition of the term "manufacture" with the words "sale or export or distribution" and the words "Drugs Technical Advisory Board constituted under section 5" in the definition of the term "patent or proprietary medicine" with the words "Central Drugs Authority".

Clause 3 inserts a new Chapter, CHAPTER IA titled "CENTRAL DRUGS AUTHORITY OF INDIA" containing proposed new sections 5 to 5M and CHAPTER IB titled "CLINICAL TRIALS" containing proposed new sections 5N to 5Q.

Proposed new section 5 provides for the constitution of the Central Drugs Authority of India, its nature, composition, location of headquarters and power to set up offices in other places in India.

Proposed new section 5A provides for qualifications of Chairperson and Members of the Central Drugs Authority.

Proposed new section 5B provides for the term of office of the Chairperson and Members of the Central Drugs Authority.

Proposed new section 5C gives the power to the Central Government for prescribing the salaries, allowances, pensions payable to, and other conditions of service of, the Chairperson and Members of the Central Drugs Authority.

Proposed new section 5D provides that any vacancy in, or any defect in the constitution of, or any defect in the appointment of the Chairperson or a Member of the Central Drugs Authority or any irregularity in its procedure not affecting the merits of a case, would not invalidate its proceedings.

Proposed new section 5E gives power to the Central Drugs Authority to appoint Drugs Controller (India) and other officers and employees of the Authority and to fix their salaries, allowances and pensions. It also provides that the Drugs Controller (India) shall be the Secretary of the Central Drugs Authority.

Proposed new section 5F enumerates the powers and functions of the Central Drugs Authority.

Proposed new section 5G provides for the powers and functions of the Drugs Controller (India).

Proposed new section 5H provides for grants to be made by the Central Government to the Central Drugs Authority.

Proposed new section 5-I provides for constitution of the Central Drugs Authority of India Fund as well as what shall be credited thereto. It also provides the purposes for which the Fund shall be applied.

Proposed new section 5J provides for maintenance of proper accounts by the Central Drugs Authority and the details regarding procedure for auditing of its accounts.

Proposed new section 5K provides for preparation of an annual report by the Central Drugs Authority, which shall be forwarded to the Central Government and also laid before each House of Parliament.

Proposed new section 5L lays down the power of the Central Government to make rules, in consultation with the Central Drugs Authority, for giving effect to the provisions as contained in CHAPTER IA.

Proposed new section 5M provides for power of the Central Drugs Authority to make regulations for discharge of its functions and exercise of its powers.

Proposed new section 5N prohibits the conduct of clinical trials in respect of any drug or cosmetic without due permission from the Central Drugs Authority.

Proposed new section 5-O provides for punishment for conducting clinical trials without permission.

Proposed new section 5P provides for procedure for trial of offences under section 5-O.

Proposed new section 5Q gives powers to the Central Government to make rules, in consultation with the Central Drugs Authority, to give effect to the provisions of CHAPTER IB.

Clause 4 provides for substitution of the existing heading of CHAPTER II of the Act with "THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE".

Clause 5 provides for omission of section 5 of the Act dealing with the Drugs Technical Advisory Board.

Clause 6 amends section 6 of the Act for substituting the word "Laboratory" with the words "Laboratory or laboratories" and the word 'Board' with the words "Central Drugs Authority".

Clause 7 amends section 7 of the Act for substituting the words "Drugs Technical Advisory Board" with the words "Central Drugs Authority". It also provides for change in the composition of the Drugs Consultative Committee.

Clause 8 omits section 7A of the Act.

Clauses 9 to 18 and clauses 20 to 27 amend various sections of the Act for replacing the word "Board", wherever it occurs, with the words "Central Drugs Authority", the words "manufacture for sale or for distribution", wherever they occur, with the words "manufacture for sale or for export or for distribution" and the words "Ayurvedic, Siddha and Unani Drugs Technical Advisory Board", wherever they occur, with the words "Central Drugs Authority", and to provide for new composition of the Ayurvedic, Siddha and Unani Drugs Consultative Committee.

Clause 19 provides for omission of section 33C of the Act dealing with the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board.

Clause 28 substitutes new section 38 dealing with laying of every rule and every regulation made under the Act before each House of Parliament within a stipulated timeframe.

FINANCIAL MEMORANDUM

Clause 3 of the Drugs and Cosmetics (Amendment) Bill, 2007 proposes to insert, *inter alia*, new section 5A in the Drugs and Cosmetics Act, 1940 empowering the Central Government to appoint the Chairperson and Members of the Central Drugs Authority of India and new section 5C in the said Act empowering the Central Government to decide on the salaries, allowances and pensions payable to, and other conditions of service of, the Members of the Central Drugs Authority of India. Some recurring expenditure will be involved in regard to payment of salaries, allowances and pensions payable to the Chairperson and Members of the Central Drugs Authority of India. The exact amount of expenditure involved will depend on the number of Members appointed and will be met out of the revenues of the Central Drugs Authority of India.

2. It is estimated that no expenditure, either of recurring or non-recurring nature, from the Consolidated Fund of India, would be involved.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 3 of the Bill proposes to insert new Chapters IA and IB (containing new sections 5 to 5Q) in the Drugs and Cosmetics Act, 1940. New section 5L proposes to confer power on the Central Government to make rules for giving effect to the provisions of Chapter IA after consultation with, or on the recommendation of, the Central Drugs Authority and after previous publication by notification in the Official Gazette. New section 5M proposes to confer power upon the Central Drugs Authority to make regulations consistent with the said Act and the rules made thereunder to discharge its functions and exercise its powers. New section 5Q proposes to confer power on the Central Government to make rules for giving effect to the provisions of Chapter IB after consultation with, or on the recommendation of the Central Drugs Authority and after previous publication by notification in the Official Gazette. Clause 7 of the Bill proposes to insert new sub-section (4) in section 7 of the said Act to confer power on the Central Government to make rules for prescribing the number of Central Government's representatives in the Drugs Consultative Committee under sub-section (2) of section 7 of the said Act, after consulation with Central Drugs Authority. Clause 26(b) (iii) of the Bill proposes to insert new clause (ff) after clause (f) in sub-section (2) of section 33N of the said Act, to confer power on the Central Government to make rules for the purpose of prescribing the number of Central Government's representatives in the Ayurvedic, Siddha and Unani Drugs Consultative Committee under sub-section (2) of section 33D of the said Act.

These matters are the matters of procedure and administrative detail. Hence, it is not practical to provide for them in the Bill. The delegation of legislative powers is, therefore, normal in character.

YOGENDRA NARAIN,
Secretary-General.

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